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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/027,792 | 12/20/2001 | John R. Adler | 1010497-991130 | 2683 |

7590 09/21/2004

MARK G. LAPPIN, P.C.
McDERMOTT, WILL & EMERY
28 STATE STREET
BOSTON, MA 02109

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| EXAMINER |
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MANTIS MERCADER, ELENI M

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| ART UNIT | PAPER NUMBER |
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3737

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,792

Applicant(s)

ADLER, JOHN R.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 06/01/2004 have been fully considered but they are not persuasive. Sirimanne et al.'904 teach marking the tissue of interest, namely breast tissue 406 which includes the cavity 404, wherein the cavity's surface necessarily is breast tissue 406 (see col. 12, lines 41-55). Therefore, the limitation or similar limitations stating "the target region comprising tissue" and the limitation "configured to anchor the fiducial apparatus within the target region" do not define over the art of record, in that if the cavity itself is considered the target region that cavity does not exist in vacuum, it is enclosed in breast tissue and at a minimum the surface of the cavity is made of breast tissue, thereby the target region or cavity includes breast tissue at least at its surface. The rejections are therefore maintained and made final. The 101 rejections are withdrawn as they have been overcome.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 10-15, 17-19 and 26-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirimanne et al.'904.

Regarding claims 1, 2, 13-14, 17-18 and 29 Sirimanne et al.'904 teaches a fiducial apparatus to be inserted into a target region, comprising:

a body portion made of a material that is visible using electromagnetic radiation, including radioopaque or echogenic (col. 2, lines 54-60); and one or more anchoring devices connected to the body portion (col. 5, lines 4-11), each anchoring device having an unanchored position and an anchored position (col. 13, lines 54-62), the unanchored position permitting the body portion to move within the target region and the anchored position anchoring the fiducial apparatus into the target region (col. 13, lines 63-67 and col. 14, lines 1-6).

Regarding claims 3 and 19, Sirimanne et al.'904 teach the body portion comprising a memory metal member that bends in response to an appropriate signal to anchor itself into the target region (see col. 13, lines 57-62).

Regarding claims 11-12 and 27-28, Sirimanne et al.'904 teach the target region comprising a target region within a human body such as a tumor (see col. 1, lines 20-58).

Regarding claims 15 and 17, Sirimanne et al.'904 teach the insertion further comprising injecting the fiducial into the target region using a needle (see device 400 in Figures 4A-4C).

Regarding claims 10 and 26, Sirimanne et al.'904 teach wherein the anchor member is an elongated rectangular shaped member that embeds into the target region (see Figure 1C).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-6 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al.'904 in view of Flomenblit et al.'641.

Regarding claims 4-5 and 20-21, Sirimanne et al.'904 do not explicitly teach that an appropriate signal further comprises an electric field or a predetermined temperature.

In the same field of endeavor, Flomenblit et al.'641 teach the use of an appropriate signal further comprising a predetermined temperature to insert a coiled structure into the area of interest (see col. 2, lines 61-67 and col. 3, lines 1-64). Note that an electric field is required to change the temperature since an electronic apparatus is used.

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al.'904 and incorporated the teachings of Flomenblit et al.'641 in order to introduce the coiled marker (such as the one indicated in Figure 5D of Sirimanne et al.'904) into the area of interest.

Regarding claims 6 and 22, Sirimanne et al.'904 teach the memory metal further comprising nitinol (see col. 13, lines 54-62).

6. Claims 7-9, 16 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al.'904 in view of Foester et al.'304.

Regarding claims 7 and 23, Sirimanne et al.'904 do not explicitly teach an anchoring device further comprising an anchor member and an elastic member connected to the anchor member that urges the anchor member into the anchored position.

In the same field of endeavor, Foester et al.'304 teach a spring structure (or an elastic member) connected to the anchor member that urges the anchor member into the anchored position (see paragraph 0019).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Sirimanne et al.'904 and incorporated the teachings of Foester et al.'304

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of incorporating a spring structure as that enhances the implantation of the marker (as explained by Foester et al.'304 in paragraph 0019).

Regarding claims 8-9 and 24-25, Foester et al.'304 teach an anchor member comprising a spike that embeds itself into the target region or a pyramidal shaped member (see Figures 17, showing multiple spikes or multiple pyramidal members).

Regarding claim 16, it would have been obvious to one skilled in the art at the time that the invention was made to have moved one or more anchor devices into an anchored position in order to embed the one or more anchor devices into the target region, depending on the size of the target of interest, requiring more marking identification, as this is a well known practice to those skilled in the art.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM